

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claim 1 (original) A device of the type useful to perform a lateral flow, immunodiagnostic assay, the device comprising;

a carrier for conducting flow of liquid sample suspected of containing an analyte of interest

one or more reagents disposed on said carrier, for detecting said analyte; and

sample deposition means associated with said carrier, said sample deposition means being adapted to deposit sample onto said carrier as a sample band that is essentially linear and is generally transverse to the desired direction of subsequent sample flow.

Claim 2 (original) A device according to claim 1, further comprising a detection channel defined downstream of said sample band, the sample band having a width greater than the detection channel, said channel further comprising an immobilized reagent for binding with said analyte or with a binding partner thereof.

Claim 3 (currently amended) A device according to claim 1 or 2, wherein said carrier comprises a sample receiving pad, an analyte detection pad, and a bridging pad connecting the sample receiving pad and analyte detection pad in flow communication.

Claim 4 (original) A device according to claim 3, further comprising a wettable barrier layer adhered to and connecting the bridging pad and the analyte detection pad.

Claim 5 (currently amended) A device according to claim 3 or 4, wherein the bridging pad is positioned in contact with and above the sample pad and detection pad.

Claim 6 (original) A device of the type useful to perform a lateral flow immunodiagnostic assay for one or more target analytes, the device comprising:

a carrier for conducting the flow of sample along a liquid path; the carrier comprising a sample receiving zone comprising a detectably labeled, mobile detector reagent for binding to the target analyte, and an analyte detection zone downstream of the sample receiving zone and comprising an immobilized capture reagent for binding with a complex formed between said analyte and said capture reagent, and

a housing for receiving the carrier, the housing comprising a sample receiving means and a sample deposition means in flow communication with the sample receiving means and the sample receiving zone, the sample deposition means being adapted to deposit liquid sample as a sample band that is essentially linear and has a width greater than the width of the analyte detection zone.

Claim 7 (original) A device according to claim 6, wherein the sample receiving zone and the analyte detection zone are defined on distinct carrier pads, and wherein said pads are coupled for sample flow by a bridging pad.

Claim 8 (original) A device according to claim 7, wherein the bridging pad and the analyte detection zone pad are connected by a wettable barrier layer that enhances capillary flow therealong.

Claim 9 (original) A device according to claim 8, wherein the bridging pad has a width narrower than the length of the sample band deposited from the sample deposition means.

Claim 10 (original) A device according to claim 8, wherein the sample deposition means comprises a sample inlet means and a sample deposition channel, for moving sample from the inlet to the sample receiving zone.

Claim 11 (original) A device according to claim 10, wherein the sample deposition channel is integrated within the housing.

Claim 12 (original) A device according to claim 10, wherein the sample deposition channel is dimensioned to promote lateral capillary flow to fill the sample deposition channel, before any substantial flow of the sample into the carrier.

Claim 13 (original) A device according to claim 12, wherein the sample deposition channel is formed substantially within the housing.

Claim 14 (original) A device according to claim 12, wherein the sample deposition channel is defined between a deposition channel defining surface and the carrier.

Claim 15 (original) A diagnostic device of the type useful to perform a lateral flow immunodiagnostic assay, the device comprising a carrier for conducting the flow of sample therealong, the carrier comprising a sample pad for receiving the sample and, in flow communication therewith, a detection pad comprising at least one reagent useful in detecting analyte in the sample, wherein the width of the sample pad is greater than the width of the detector pad.

Claim 16 (original) A diagnostic device according to claim 15, wherein the carrier further comprises a bridging pad, and further wherein the bridging pad couples the sample pad and the detector pad in flow communication.

Claim 17 (original) A diagnostic device according to claim 16, wherein each pad in said carrier comprises a water-impermeable backing layer and a sample conducting face,

and further wherein the sample conducting face of the bridging pad is in contact with the sample conducting faces of each of the detection pad and the sample pad.

Claim 18 (currently amended) A diagnostic device according to claim 16 or ~~17~~, wherein the bridging pad and the detection pad are coupled in flow communication by an upper barrier layer of water-impermeable material that is either translucent or transparent.

Claim 19 (currently amended) A diagnostic device according to ~~any one of claims 15–18~~, further comprising a housing adapted to deposit sample onto said sample pad as a generally linear band having an axis that is transverse to the direction of sample flow and is wider than the width of the detection pad.

Claim 20 (original) A diagnostic device for testing a liquid sample, the device comprising:

- (a) a carrier for receiving at least a portion of the sample; and
- (b) a sample delivery means, said sample delivery means having a delivery channel that is in fluid communication with the carrier, said delivery channel having a first delivery channel surface facing a second delivery channel surface, wherein said first delivery channel surface is spaced apart from said second delivery channel surface by a distance that promotes longitudinal advancement of the sample along the delivery channel by capillary action.

Claim 21 (original) The device of claim 20, wherein the distance between the first delivery channel surface and the second delivery channel surface is less than 0.5 mm.

Claim 22 (original) The device of claim 21, wherein the distance between the first delivery channel surface and the second delivery channel surface is less than 1.0 mm.

Claim 23 (currently amended) The device of claim 20, ~~21 or 22~~, wherein the delivery channel has an inlet and an outlet, wherein at least a portion of the sample received at the inlet advances between the first delivery channel surface and the second delivery channel surfaces toward the outlet.

Claim 24 (currently amended) The device of claim 20, ~~21, 22 or 23~~, wherein the delivery channel is in fluid communication with a sample deposition means, wherein at least a portion of the sample received at the outlet of the delivery channel flows to the sample deposition means.

Claim 25 (original) The device of claim 24, wherein the sample deposition means includes a deposition channel, said deposition channel having a deposition channel defining surface facing the carrier and defining the deposition channel, and wherein the deposition channel has a depth that promotes lateral distribution of the sample along the deposition channel by capillary action, thereby to form a sample band across the carrier.

Claim 26 (original) The device of claim 25, wherein the depth of the deposition channel between the deposition channel defining surface and the carrier is less than 0.5 mm.

Claim 27 (original) The device of claim 26, wherein the depth of the deposition channel between the deposition channel defining surface and the carrier is less than 1.0 mm.

Claim 28 (currently amended) The device of ~~any one of~~ claims 25 to ~~27~~, wherein the first delivery channel surface is formed with an advancement groove, wherein at least a portion of the sample received at the inlet advances within the advancement groove along the delivery channel to the outlet.

Claim 29 (original) The device of claim 28, wherein the advancement groove extends beyond the outlet of the delivery channel to promote the flow of at least a portion of the sample into the sample deposition channel.

Claim 30 (currently amended) The device of ~~any one of~~ claims 24 to 29, wherein the delivery channel is generally rectilinear.

Claim 31 (currently amended) The device of ~~any one of~~ claims 24 to 30, wherein the volumetric capacity of the sample delivery means provides a sufficient amount of liquid sample for the testing.

Claim 32 (currently amended) The device of ~~any one of~~ claims 24 to 31, including a housing enclosing the carrier, wherein the sample delivery means and the sample deposition means are formed in the housing.

Claim 33 (original) The device of claim 32, wherein the housing comprises a base member and an upper member, wherein the first delivery channel surface is provided on the base member and the second delivery channel surface is provided on the upper member.

Claim 34 (original) The device of claim 33, wherein the base and upper members include abutting surfaces determining the distance between the first and second delivery channels.

Claim 35 (currently amended) The device as claimed in ~~any one of~~ claims 20 to 34, wherein the carrier includes at least one detachably labeled, mobile reagent for binding with a target analyte and, at a position downstream thereof, at least one immobilized capture reagent for binding with the target analyte or a complex formed therewith.

Claim 36 (original) A diagnostic device for testing a liquid sample, the device comprising:

- (a) a carrier for receiving at least a portion of the sample; and
- (b) a sample injection means, said sample injection means having an injection channel that is in fluid communication with the carrier.

Claim 37 (original) The device of claim 38, wherein the injection channel is in fluid communication with a sample delivery means, and wherein at least a portion of the sample received in the sample delivery means flows into the injection channel.

Claim 38 (original) The device of claim 37, wherein the sample delivery means includes an advancement groove, wherein the advancement groove extends into the injection channel to promote the flow of at least a portion of the sample into the injection channel.

Claim 39 (original) The device of claim 38, wherein the volumetric capacity of the injection channel provides a sufficient amount of liquid sample for the testing.

Claim 40 (original) The device of claim 36, wherein the carrier includes at least one detectably labeled, mobile detection reagent for binding to a target analyte, and, downstream therefrom, at least one immobilized capture reagent for binding with a complex formed by a corresponding mobile detection reagent and said target analyte.